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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,333	07/26/2001	Franco Pamparana	101615-00012	5701

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,333

Applicant(s)

PAMPARANA, FRANCO

Examiner

Raymond J. Henley III

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-14, 16, 18-20, 22, 24, 27, 28 and 30-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-14, 16, 18-20, 22, 24, 27, 28 and 30-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

**CLAIMS 12-14, 16, 18-20, 22, 24, 25, 27, 28 AND 30-35 ARE PRESENTED FOR
EXAMINATION**

Applicant's "Response to Office Action" filed December 5, 2005 has been received and entered into the application. Accordingly, claims 31, 32 and 35 have been amended.

In light of the above amendments, as well as Applicant's remarks at page 6 of the above referenced response, (under the heading "Claim Amendments"), the objection to claims 31, 32, 34 and 35 is withdrawn.

Claim Rejection - 35 USC § 103

Claims 12-14, 16, 18-20, 22, 24, 27, 28 and 30-35 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Breivik et al. (U.S. Patent No. 5,502,077) in view of Harrison's Principles of Internal Medicine ("Harrison's"), each of record, for the reasons of record as set forth in the previous Office action dated October 21, 2005, at pages 2-7, which reasons are here incorporated by reference.

Applicant's remarks at pages 6-10 of the above referenced response have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

Applicant's present remarks appear essentially the same as those previously presented in the response filed August 11, 2005. Therefore, the Examiner will not reiterate his position with respect to such remarks so as to provide for a clear record.

As set forth above, the Examiner maintains his position that the presently claimed subject matter would have been obvious in light of the references and remarks made by the Examiner in the previous Office actions. Contrary to Applicant's opinion, this conclusion of obviousness

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rests upon clear teachings in the references and sound scientific reasoning which is consistent with the requirements for a conclusion of obviousness under 35 U.S.C. § 103 as mandated by the Courts and the Office, (see, for example, MPEP §§ 2141-2144.04).

Having stated the above, the Examiner will take this opportunity to further expand upon his position stated in the previous Office action dated October 21, 2005, at page 4 that:

“It remains the Examiner’s position that based on the teachings of Breivik et al. and Harrison's, the selection of any specific patient population in whom to practice the invention of Breivik et al., such as patients who have suffered myocardial infarction, would have been a matter well within the purview of the skilled artisan.

This position is stated and expanded upon in the previous Office actions, e.g., see the Office action dated May 23, 2005 at page 2-5.”

That the above is allegedly inaccurate appears central to Applicant’s position as presented throughout both the most recent response and the one before that. It appears to the Examiner, however, that in considering the patient population put before one of ordinary skill in the art in whom to practice the invention of Breivik et al., (taken with the teachings of Harrison’s), the artisan would have had but only two choices, the first population being those who have not had previously suffered a myocardial infarction and those who had previously suffered a myocardial infarction. Given such a small genus of population, it is bordering on, if not actually touching, anticipation of this element of the claimed subject matter that the treatment of one group or the other would have been recognized and placed in the possession of the public.

Such a position would appear consistent with MPEP § 2131.02 regarding genus-species situations. While the MPEP speaks of chemical compounds, the essence of that portion is that

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where the genus is sufficiently small, the species making up such genus would have been anticipated, e.g., “In *In re Schauman*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978), claims to a specific compound were anticipated because the prior art taught a generic formula embracing a limited number of compounds closely related to each other in structure and the properties possessed by the compound class of the prior art was that disclosed for the claimed compound. The broad generic formula seemed to describe an infinite number of compounds but claim 1 was limited to a structure with only one variable substituent R. This substituent was limited to low alkyl radicals. One of ordinary skill in the art would at once envisage the subject matter within claim 1 of the reference.).”, MPEP *Id.* Here, as set forth above, there are only two members of the patient population from which to choose and it may well be said that both members would have been once envisaged.

New to the record is Applicant’s position at pages 9-10 of the recent response that “The Examiner is applying an improper ‘obvious to try’ rationale”.

In response thereto, the Examiner looks to MPEP § 2145(X)(B), wherein it is stated: “The admonition that ‘obvious to try’ is not the standard under § 103 has been directed mainly at two kinds of error. In some cases, what would have been ‘obvious to try’ would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.... In others, what was ‘obvious to try’ was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.’ *In re O’Farrell*, 853 F.2d 894,

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903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988)".

Here, the differences between the claimed subject matter and that of the prior art are not seen to rise to a situation where there are "numerous possible choices" or where there is a new technology to explore. The art relied on, as well as the Examiner's assessment of such art, makes it clear that it would have been "obvious to do" what Applicant is claiming. Protecting *anyone* from a myocardial infarction would have been a motive well established in the medical art, whether actually stated in the art or not. The selection of a given population, i.e., in those people who have suffered a myocardial infarction, has not been objectively established as being critical or otherwise non-obvious. Therefore, it remains the Examiner's position that the selection of any particular patient in whom to practice the methods of the prior art would have been well within the purview of the skilled artisan. Further, because of the small genus of population that would have been before the skilled artisan, the present conclusion of obviousness is even more difficult to avoid.

Accordingly, for the reasons above and those of record, the Examiner will maintain his position and the rejection as being proper.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period


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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond J Henley III
Primary Examiner
Art Unit 1614

March 7, 2006